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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,170	02/27/2004	Alain Fouere	P24980	4885
7055	7590	05/19/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 05/19/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/787,170		FOUERE ET AL.	
	Examiner		Art Unit	
	Patricia M. Bianco		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant filed an amendment 2/21/06, where portions of the specification were amended, new figures 11 & 12 were added, and claims 1 and 19 were amended.

Claims 1-23 remain pending.

Drawings

The drawings were received on 2/21/06. These drawings are approved.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-9, 11, & 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al. (6,629,533). Webb et al. disclose a punctum plug and method for inserting the punctum plug using an insertion tool. The punctum plug (110/210/310/410/510) has a body or shaft that is substantially cylindrical with an axial bore therethrough for the passage of an insertion tool, and one or more flexible anchoring arms or elements attached to the external wall of the plug. The anchoring arms are flexible enough to fold during the insertion procedure and then straighten out once in place. The anchoring arms function to retain the plug in the patient's punctum. As is shown in the figures, the anchoring arms may be in the shape of radial arms (or pins) and may be of the same length, different lengths, or varying lengths. The plug may have one or more disks. These anchoring arms are seen to be equivalent to applicant's pins, since they extend radially outward from the body in a helical formation, are of a constant length, and serve to reinforce & stabilize the apparatus within the punctum. The shape is seen to be in the form of a cone (see figures 2-7). The apparatus is made of flexible material. Webb et al. discloses a method of inserting the plug into the punctum using an insertion tool.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 15, & 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of MacKeen et al. (4,915,684). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that punctum plug has an axial duct for the passage of tears and that the insertion tool used for inserting the plug is a push rod.

MacKeen et al. discloses a punctum plug and a method for inserting the plug. The plug comprises a body that is substantially cylindrical and has an axial bore or duct for the passage of tears. MacKeen et al. teaches that an insertion tool that is a dilating rod (i.e. push rod) is used to insert the plug into the punctum (see figures 5A-E). At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the plug of Webb et al. to include an open axial duct as taught by MacKeen et al. to meter the passage of lacrimal fluid (or tears) away from the eye, through the punctum while the plug was inserted.

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Freeman (3,949,750). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the insert is made of metal or shape memory metal. Freeman discloses a punctum plug that may be made of stainless steel or other inert metal material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of either stainless steel as taught by Freeman or to be made of or Nitinol (shape memory material), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Freeman discloses to use metal for punctum plugs and it is well known in the art to use shape memory metals such as Nitinol, since both are well received by the body.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Herrick (5,163,959). Webb et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the insert is made of a radio-opaque material that is visible with X-rays. Herrick discloses a canalicular implant that may be made of a material that is responsive to X-rays to aid in determining if the implant is properly located within the canaliculi during implantation (col. 13, lines 46-50). It would have been obvious to one having ordinary

Art Unit: 3761

skill in the art at the time the invention was made to modify the implant of Webb et al. to be made of a material that is responsive to X-rays as taught by Herrick, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

Claims 16, 17, 22, & 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. ('533) in view of Seder et al. (4,959,048). Webb et al. discloses the invention substantially as claimed, see rejection of claim 1 above, however, fails to disclose specifically that the tool used to implant the plug includes jaws. Seder et al. discloses using a forceps for insertion of the plug. A forceps is considered to have jaws. It would have been an obvious matter of design choice to modify the method of insertion of Webb et al. to substitute the forceps as the tool, as taught by Seder et al., since applicant has not disclosed that using a forceps device solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well.

Response to Arguments

Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone


Art Unit: 3761

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 14th, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761



PATRICIA BIANCO
PRIMARY EXAMINER